Atty Docket: 31-CD-5530

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

G. Ian Rowlandson : Group Art Unit: 3626

Serial No.: 09/751,023 : Examiner: Gottschalk, M. A.

Filed: December 29, 2000

Title: AUTOMATED SCHEDULING OF EMERGENCY PROCEDURE BASED ON IDENTIFICATION OF HIGH-RISK PATIENT

Hon. Commissioner for Patents
Alexandria, VA 22313-1450

DECLARATION OF INVENTOR
PURSUANT TO 37 CFR § 1.132

I, IAN ROWLANDSON, hereby declare as follows:

I am the sole inventor of the invention described and claimed in the above-referenced patent application. I am submitting this declaration for the purpose of clarifying the teachings of the prior art applied by the Examiner in the Final Office Action dated October 5, 2006.

Fujimoto Reference

U.S. Patent No. 5,339,821 to Fujimoto discloses a home medical system that allows a person to measure his or her daily condition at home. The home medical system includes equipment for measuring the electrocardiogram and other heart conditions of a user and a communication link for connecting the user's equipment to a medical institution so that medical personnel can review the measured results obtained by the user. Figure 6 shows the steps

of a procedure for measurement of an electrocardiogram. The user puts two measuring electrodes 18 (see Figures 2 and 4 of Fujimoto) on his/her arms (see col. 5, lines 36-38). An acute coronary syndrome (ACS) cannot be detected via a pair of measuring electrodes.

In contrast, the instant patent application clearly refers to a 12-lead electrocardiogram. For example, the paragraph at lines 28-35 on page 10 states that the preferred embodiment of the invention uses applications software that comprises "the previously described 12SL® program." As previously described on page 2, lines 8-10, the 12SL® program "is a computer program for analyzing simultaneously acquired 12-lead ECGs." More than a pair of electrodes is necessary for measuring the contour of the waves. An analysis of the contour across 12-leads is necessary for the recognition of ACS. Accordingly, it would not have been obvious to a person skilled in the art to use the home medical system of Fujimoto to detect ACS.

Coolidge Reference

U.S. Patent Appln. Publ. No. 2002/0107206 to Coolidge is focused on the treatment of ACS, not the diagnosis of ACS. Furthermore, that treatment is only relevant to those ACS patients who are not suffering from a myocardial infarction (MI), for example, the Summary of the Invention section, which states that one object of Coolidge's invention is "[a] method of

treating a patient suffering from acute coronary syndrome, comprising administering to the patient a therapeutically effective amount of a GLP-1 molecule, wherein the patient is not suffering from a Q-wave MI" (see ¶ [0011]). Coolidge does not teach the diagnosis of ACS employing the electrocardiogram. Although it states such ACS terms as Q-wave MI (as diagnosed by ECG), it does not describe how a Q-wave MI is recognized from the ECG. Rather, Coolidge teaches the stratification of an ACS diagnosis based on additional blood tests known as cardiac biomarkers (specifically, troponin and creatine kinase). Obviously, the requirement for blood testing is inconsistent with the teach of Fujimoto, in which the patient operates a medical system located at his/her home. There is no disclosure in Fujimoto that the patient can test his/her own blood at his/her home. Accordingly, it would not be obvious to a person skilled in the art combine the teaching of Coolidge with the teaching of Fujimoto.

Ironically, the treatment described in Coolidge is not appropriate for those patients that are recognized by the instant patent application. The instant application detects a different form of an ACS patient: that is, those that have an ECG that exhibits ST elevation or a pattern commensurate with a Q-wave, ST elevated acute myocardial infarction. In fact, Coolidge prefers those that exhibit a normal ECG.

In contrast to the patients defined by Coolidge, patients positively identified by the ECG as a Q-wave, ST elevated acute myocardial infarction (STEMI) require an immediate emergency procedure in a catheterization lab as described in the instant application. Frankly, for the STEMI patient group it would be dangerous, as defined by the American College of Cardiology, to administer a GLP-1 that "can be self-administered, and can be administered in one or more doses, as needed, on an intermittent or continuous basis, to optimize metabolism in cardiac tissue and to prevent cardiac damage associated with ischemia."

Bayne Reference

U.S. Patent Appln. Publ. No. 2005/0060198 to Bayne discloses a system having the object of enabling people "to receive acute care in their home or workplace" (see Bayne, ¶ 0007). This is completely different than applicant's claimed invention in which acute care, namely, surgery involving the insertion of a catheter, is provided in a catheterization lab.

The Bayne publication states:

> The invention affords its users with a number of distinct advantages. Importantly, the provision of in-home medical services enhances the bond between patient and doctor, as the doctor enters the patient's home and receives the patient's trust. Also, the provision of on-site medical services saves time of busy people, since they can avoid having to drive to the hospital and wait for medical attention and prescription filling. This invention also enables doctors to save money by avoiding the substantial overhead costs of maintaining traditional medical offices. Patients also save money by receiving at-home care rather than hospital commitment, ambulance services, or emergency room visits. This invention is especially useful for elderly or other infirm patients that simply cannot travel to the doctor's office. Also, in non-life threatening cases, the invention helps non-ambulatory patients obtain medical care without the flashing lights, sirens, costs, and other excessive attributes of ambulance service. By providing in-home care, the method of this invention also encourages more rapid discharge of patients after surgery. As another benefit, the invention can be used to provide on-site medical services for sporting events, air shows, beaches, and other public gatherings.

All of these advantages of the Bayne system derive from provision of medical care at a remote location away from a central medical facility. Thus the idea of examining patients and then scheduling surgery for ACS at a catherization lab, as disclosed in the instant application, is completely different and even opposite to the teaching of Bayne.

Furthermore, Bayne discloses one embodiment in which the patient at his home initiates a call to a call center and another embodiment where an Internet-capable medical device 106 (see Bayne, Fig. 1) automatically requests that the call center send a

clinician to the patient's home, e.g., in response to detection of a medical condition such as dangerously low blood pressure (see Bayne, ¶ 0078). In either embodiment, when there is sufficient information to process the notification, a triage processing block 114 at the call center 110 determines whether the patient's situation constitutes a life-threatening emergency. However, this criticality determination must be made without the benefit of blood testing, since obviously neither the patient at his home nor the medical device 106 is capable of testing the patient's blood. Nor does Bayne disclose that the medical device 106 is capable of acquiring a 12-lead ECG. In other words, according to the teaching of Bayne, prior to the dispatch of a clinician to the patient's home or workplace, there is insufficient information from the patient to diagnose acute coronary disease. Moreover, in view of the aforementioned advantages of the home medical care, a person skilled in the art would not be motivated by the Bayne teaching to conceive of a method or system for surgery for ACS using a catheter, which requires the patient's presence at a central medical facility.

In addition, the Examiner states that Bayne discloses the use of expert system software operating on ECG data for determining whether the patient has a high probability of acute coronary syndrome. This characterization of the Bayne teaching is clearly erroneous. The expert system software, mentioned in ¶ 0073 of

Bayne, is part of the triage processing block, which operates based only on the limited information provided by the patient or by the aforementioned remotely located home medical device 106, i.e., based on information that does not include 12-lead ECG data. Thus, one cannot infer that the expert system software of Bayne is capable of determining that the remotely located patient has acute coronary syndrome because the information necessary to such determination is clearly absent. Moreover, it must be noted that the words "acute coronary syndrome" and "catheterization" appear nowhere in Bayne.

In accordance with the teaching of Bayne, whether or not a clinician is sent is determined by the triage processing block 114 located at a call center.

> The triage processing block 114 includes personnel and/or equipment trained or programmed to receive incoming calls, assess whether the reported medical condition is appropriate for treatment by mobile care entity's clinicians. ... The triage processing block 114, however, refers life-threatening conditions to more appropriate ambulance, life-flight, or other critical care services.

[Bayne, ¶ 0032.] Thus, the triage processing block 114 responds to a call for medical assistance by determining whether emergency services or a medical care clinician should be sent to the patient. In the former case, the triage processing block 114 directs the web server 113 to display a message instructing the patient to obtain emergency ambulance services, for example, by

dialing "911". [Bayne, ¶ 0071.] In other words, the patient must fend for him/herself and the triage processing block takes no steps to provide emergency medical treatment.

¶ 0073 of Bayne discloses that the triage processing block "determines the appropriate clinician type and equipment required to treat the patient's reported condition." However, as seen in Figure 4 of Bayne, this occurs only if a determination has been made during triage that there is no emergency. Obviously, acute coronary syndrome is an emergency, in which case the triage processing block would never get to step 418 of determining the required clinician type. In an emergency, no clinician is sent to the patient's home. Therefore the Bayne system does not envision calling a cardiologist to go to the patient's home if the patient is suffering from acute coronary syndrome.

Thus, Bayne teaches away from providing a computer that will analyze ECG data to determine whether the patient is suffering from acute coronary syndrome. Nor does Bayne teach anything about automated scheduling. The Examiner cites ¶ 0098 of Bayne for the proposition that the clinician can utilize the clinician device to complete an on-line hospital admission process. Purportedly, this would take the form of the clinician providing a predetermined message and "the clinician device - i.e., a computer - scheduling the procedure" (page 5 of action). This rationale is flawed. In the first place, admission to a hospital is not the same thing as scheduling "an emergency procedure". The term "scheduling" implies the setting of a time and place for the emergency procedure. Bayne neither discloses nor suggests this.

Summary

The instant application describes the use of serial ECG analysis to detect specific diagnostic emergency conditions such as a new left bundle branch block, which may be due to acute myocardial infarction. The instant application teaches a configurable technology for routing ECG analysis information to the appropriate care provider in order to effectively activate a catheterization lab for emergency care. In response to an alert, expedited treatment for acute myocardial infarction is provided. A person skilled in the art would not view the home care systems of

Fujimoto and Bayne as suggesting providing emergency treatment for ACS in a hospital setting.

The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole inventor: IAN ROWLANDSON

Inventor's signature:  27 FEB 07
DATE

Residence: Milwaukee, Wisconsin
Citizenship: United States of America
Post Office Address: 7641 North Santa Monica Blvd.
Milwaukee, WI 53217